

Claims

1. A lyophilized composition comprising a physiologically active substance and a
5 stabilizer, characterized in that the stabilizer is a recombinant or synthetic gelatin-
like polypeptide comprising at least one stretch of 10 or more consecutive repeats of
Gly-Xaa-Yaa triplets and in which at least 20% of the amino acids are present in the
form of consecutive Gly-Xaa-Yaa triplets and wherein said recombinant
polypeptide has a calculated glass transition temperature of higher than 180 degrees
10 Celsius.
2. A composition as in claim 1 wherein said recombinant or synthetic gelatin-like
polypeptide has a molecular weight between 3,000 Dalton and 80,000 Dalton
preferably between 5,000 Dalton and 60,000 Dalton and more preferably between
10,000 and 40,000 Dalton.
- 15 3. A composition as in claim 1 wherein said recombinant or synthetic gelatin-like
polypeptide has a molecular weight between 3,000 Dalton and 15,000 Dalton
preferably between 5,000 Dalton and 10,000 Dalton and more preferably between
6,000 and 8,000 Dalton.
4. A composition as in the preceding claims wherein the glass transition temperature
20 of the recombinant or synthetic gelatin-like polypeptide is higher than 190 degrees
Celsius preferably higher than 200 degrees Celsius
5. A composition as in the preceding claims wherein the recombinant or synthetic
gelatin-like polypeptide has a bimodal molecular weight distribution
6. A composition as in the preceding claims wherein the recombinant or synthetic
25 gelatin-like polypeptide is free from helical structure
7. A composition as in the preceding claims wherein the number of hydroxyproline
residues in the recombinant or synthetic gelatin-like polypeptide is less than 5% of
the total number of amino acid residues preferably less than 2%
8. A recombinant or synthetic gelatin-like polypeptide comprising at least one stretch
30 of 10 or more consecutive repeats of Gly-Xaa-Yaa triplets and in which at least
20% of the amino acids are present in the form of consecutive Gly-Xaa-Yaa triplets
and wherein said recombinant gelatin-like polypeptide has a calculated glass
transition temperature of higher than 180 degrees Celsius.

9. Process for lyophilizing compositions comprising a physiological active substance and a stabilizer characterized in that the stabilizer is a recombinant or synthetic gelatin-like polypeptide comprising at least one stretch of 10 or more consecutive repeats of Gly-Xaa-Yaa triplets and in which at least 20% of the amino acids are present in the form of consecutive Gly-Xaa-Yaa triplets and less than 5% of the total number of amino acid residues are hydroxyproline residues and wherein said recombinant gelatin-like polypeptide has a calculated glass transition temperature of higher than 180 degrees Celsius.